

Dade Behring Marburg GmbH
P. O. Box 11 49
35001 Marburg, Germany
www.dadebehring.com

Phone: +49 (6421) 39-4601
Fax: +49 (6421) 39-4594

To whom it may concern

Our Ref.
BR-27204.doc

Ext.
06421-39-4601

Fax
06421-39-4594

Date
December 21, 2004

Field Correction
on
Thromborel® S (OUHP)
Lot Numbers 505696B, 505696C, 505697B, 505697C, 505698B,
505699B, 505699C, 505699D, 505701B and 505701C

Dear Thromborel® S Customer:

Our records indicate that you have received one of the above listed Thromborel® S (OUHP) lot numbers. The purpose of this letter is to inform you that certain ISI values provided in the table of assigned values for the Sysmex* CA-500 series instruments are incorrect and may lead to erroneously increased INR values.

Below please find the correct ISI values for the above listed lots when using the Sysmex* CA-500 series instrument with software versions up to and including 00-09:

Thromborel® S LOT	ISI (CA-500 series up to and including software version 00-09)
505696B, 505696C	1.07
505697B, 505697C	1.01
505698B	1.01
505699B, 505699C, 505699D	1.02
505701B, 505701C	1.00

If you are using a Sysmex* CA-500 series instrument with software version up to and including 00-09 with one of these lots of Thromborel® S, please use the above ISI values and do not use the ISI value provided in the Table of assigned Values. If you are using some other system or a Sysmex CA-500 series instrument with a software version greater than 00-09, you should use the ISI values provided in the Table of assigned values.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you have transferred this product.

*Sysmex is a registered trademark of SYSMEX CORPORATION in the USA, in Germany and other countries

We apologize for the inconveniences this action causes and thank you for your continued support of Dade Behring Hemostasis products.

Sincerely

Original signature is on file

.....
Dr. Norbert Dedner
Director
Field Quality Assurance

Original signature is on file

.....
Michael Nöh
Director
Hemostasis Global Marketing